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1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,744	NEFFGEN ET AL.	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/7/10*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/1/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Angeletakis *et al.* (US 6,121,344).

Regarding claims 1-10, 12-14: Angeletakis *et al.* teaches dental composite resin (1:10-18), with example A (8:15-30) comprising 27.6 wt% of Resin containing bisphenol A diglycidyl ether dimethacrylate, triethyleneglycol dimethacrylate, camphorquinone, and 2-ethyhexyl-4-(dimethylamino)benzoate (6:52-65; Table 2); 63.7 wt% of silanated {{γ-methacryloxypropyltrimethoxysilane} barium aluminoborosilicate having a mean particle size of 0.62 μm {prepared by milling (ground) (5:35-6:36), radiopaque (8:31-45; Table 4)}; 5.0 wt% of silanated {γ-methacryloxypropyltrimethoxysilane} OX-50 fumed silica having an average particle size of 0.04 μm {40 nm}, and 3.7 wt% of TS-530 heaxmethyldisilazane treated fumed silica (7:37-44) having an average particle size of 0.02 μm {20 nm}.

Note: the instant specification discloses feature b) of the claim is obtained after the nanoscale filler is incorporated into the binder {see specification, pg. 3, ln. 20-24; pg. 5, ln. 17-27; pg. 24, ln. 12-19}. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) [See MPEP 2113].

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. the nanoscale filler having at least 20 particle number% of nanoparticles as aggregated particles, would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Angeletakis *et al.* (US 6,121,344).

Regarding claim 15: Angeletakis *et al.* teaches a process for preparing dental composite resin for use in dental restoratives (1:10-27; example A; 8:15-30), the composite resin was prepared by mixing: 27.6 wt% of Resin containing bisphenol A diglycidyl ether dimethacrylate, triethyleneglycol dimethacrylate, camphorquinone, and 2-ethyhexyl-4-(dimethylamino)benzoate (6:52-65; Table 2); 63.7 wt% of silanated {{γ-methacryloxypropyltrimethoxysilane} barium aluminoborosilicate having a mean particle size of 0.62 μm {prepared by milling (ground) (5:35-

6:36)}; 5.0 wt% of silanated OX-50 fumed silica having an average particle size of 0.04 μm {40 nm}, prepared by silanating agglomerated OX-50 fumed silica with γ-methacryloxypropyltrimethoxysilane (7:25-35); and 3.7 wt% of TS-530 heaxmethyldisilazane treated fumed silica (7:37-44) having an average particle size of 0.02 μm {20 nm} (example A; 8:15-30) [the resin was prepared; OX-50 fumed silica (40 nm) was treated with γ-methacryloxypropyltrimethoxysilane; barium aluminoborosilicate (0.62 μm) was prepared by milling (ground); the silanated fillers and Resin were thoroughly mixed]; and the samples were cured into a dental composite (8:62-66) for stress/load bearing restorations (9:12-10;21; 11:14-24) such as crowns, inlays, onlays, fillings, etc (1:10-27).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. incorporation of the nanoscale filler into the organic binder until at least 50 wt% of nanoscale filler has a particle diameter of less than 200 nm, would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Claims 16-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Angeletakis *et al.* (US 6,121,344).

Regarding claims 16-24 and 26: Angeletakis *et al.* teaches process for the production of a dental composite resin (1:10-27; example A; 8:15-30), the composite resin was prepared by mixing: 27.6 wt% of Resin containing bisphenol A diglycidyl ether dimethacrylate, triethyleneglycol dimethacrylate, camphorquinone, and 2-ethyhexyl-4-(dimethylamino)benzoate (6:52-65; Table 2); 63.7 wt% of silanated {{γ-methacryloxypropyltrimethoxysilane} barium aluminoborosilicate having a mean particle size of 0.62 μm {prepared by milling (ground) (5:35-6:36)}; 5.0 wt% of silanated OX-50 fumed silica having an average particle size of 0.04 μm {40 nm}, prepared by silanating agglomerated OX-50 fumed silica with γ-methacryloxypropyltrimethoxysilane {polymerizable; i.e. a binder} by spraying in a V-blender (7:25-35); and 3.7 wt% of TS-530 heaxmethyldisilazane treated fumed silica (7:37-44) having an average particle size of 0.02 μm {20 nm} (example A; 8:15-30) [the resin was prepared; OX-50 fumed silica (40 nm) was treated with γ-methacryloxypropyltrimethoxysilane by spraying in a V-blender; barium aluminoborosilicate (0.62 μm) was prepared by milling (ground); the silanated fillers and Resin were thoroughly mixed]; and the samples were cured into a dental composite (8:62-66) for stress/load bearing restorations (9:12-10;21; 11:14-24) such as crowns, inlays, onlays, fillings, etc (1:10-27).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. incorporation of the nanoscale filler into the organic binder until at least 50 wt% of nanoscale filler has a particle diameter of less than 200 nm, would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case:

(1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angeletakis *et al.* (US 6,121,344) as applied to claim 1 above, and further in view of Teramae *et al.* (US 2002/0022677); or further in view of Sato (US 5,773,489).

Regarding claim 11: Angeletakis *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1].

Angeletakis *et al.* does not teach the filler of instant claim 11. However, Teramae *et al.* teaches dental composite materials (¶ 1) comprising organo-inorganic fillers (¶ 36) prepared by polymerization-covering the surface of an inorganic filler or aggregate filler (¶ 24, 31-33) with a polymerizable monomer, and then grinding it to a proper particle size of 0.5 to 30 μm (¶ 24, 31, 36). Angeletakis *et al.* and Teramae *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation dental composite resins. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 0.5 to 30 μm organo-inorganic fillers, as taught by Teramae *et al.* in the invention of Angeletakis *et al.*, and would have been motivated to do so since Teramae *et al.* suggests that such organo-inorganic fillers are known fillers generally used in dental composites (¶ 36).

Alternatively, Angeletakis *et al.* does not teach the filler of instant claim 11. However, Sato teaches dental composite materials (1:5-15) comprising inorganic-organic composite fillers having a particle size of 0.1 to 50 μm (7:33-49; 8:65-9:25). Angeletakis *et al.* and Sato are analogous art because they are concerned with a similar technical difficulty, namely the preparation dental composite resins. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 0.1 to 50 μm inorganic-organic composite fillers, as taught by Sato in the invention of Angeletakis *et al.*, and would have been motivated to do so since Sato suggests that such inorganic-organic composite fillers provide dental restorative materials having superior mechanical strength and abrasion resistance and a suitable consistency and handling, shows a coefficient of thermal expansion close to teeth and a low shrinkage value, and exhibits a suitable transparency and surface smoothness (3:35-43; 29:1-11).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angeletakis *et al.* (US 6,121,344) as applied to claim 16 above, and further in view of Teramae *et al.* (US 2002/0022677); or further in view of Sato (US 5,773,489).

Regarding claim 25: Angeletakis *et al.* teaches the basic claimed composition [as set forth above with respect to claim 16].

Angeletakis *et al.* does not teach the filler of instant claim 11. However, Teramae *et al.* teaches dental composite materials (¶ 1) comprising organo-inorganic fillers (¶ 36) prepared by polymerization-covering the surface of an inorganic filler or aggregate filler (¶ 24, 31-33) with a polymerizable monomer, and then grinding it to a proper particle size of 0.5 to 30 μm (¶ 24, 31, 36). Angeletakis *et al.* and Teramae *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation dental composite resins. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 0.5 to 30 μm organo-inorganic fillers, as taught by Teramae *et al.* in the invention of Angeletakis *et al.*, and would have been motivated to do so since Teramae *et al.* suggests that such organo-inorganic fillers are known fillers generally used in dental composites (¶ 36).

Alternatively, Angeletakis *et al.* does not teach the filler of instant claim 11. However, Sato teaches dental composite materials (1:5-15) comprising inorganic-organic composite fillers having a particle size of 0.1 to 50 μm (7:33-49; 8:65-9:25). Angeletakis *et al.* and Sato are analogous art because they are concerned with a similar technical difficulty, namely the preparation dental composite resins. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 0.1 to 50 μm inorganic-organic composite fillers, as taught by Sato in the invention of Angeletakis *et al.*, and would have been motivated to do so

since Sato suggests that such inorganic-organic composite fillers provide dental restorative materials having superior mechanical strength and abrasion resistance and a suitable consistency and handling, shows a coefficient of thermal expansion close to teeth and a low shrinkage value, and exhibits a suitable transparency and surface smoothness (3:35-43; 29:1-11).

Response to Arguments

Applicant's arguments filed 7/7/10 have been fully considered but they are not persuasive. The rejection of claims 1-10 and 12-14 based upon Angeletakis *et al.* (US 6,121,344) is maintained for reason of record and the following response {note the rejection of claim 15 based upon Angeletakis *et al.* (US 6,121,344) and claims 16-24 and 26 based upon Angeletakis *et al.* (US 6,121,344) will also be addressed under this heading as Applicants' argued 1-10, 12-24 and 26 collectively}.

Angeletakis *et al.* (US '344) disclose example A (8:15-30) comprising 27.6 wt% of Resin containing bisphenol A diglycidyl ether dimethacrylate, triethyleneglycol dimethacrylate, camphorquinone, and 2-ethyhexyl-4-(dimethylamino)benzoate (6:52-65; Table 2); 63.7 wt% of silanated {{γ-methacryloxypropyltrimethoxysilane} barium aluminoborosilicate having a mean particle size of 0.62 μm {prepared by milling (ground) (5:35-6:36), radiopaque (8:31-45; Table 4)}; 5.0 wt% of silanated {γ-methacryloxypropyltrimethoxysilane} OX-50 fumed silica having an average particle size of 0.04 μm {40 nm}, and 3.7 wt% of TS-530 heaxmethyldisilazane treated fumed silica (7:37-44) having an average particle size of 0.02 μm {20 nm}.

As claimed, claim 1 recites at least 50% by weight of the nanoparticles having a particle diameter of less than 200 nm (ln. 6-7); at least 20 particle number% of the nanoparticles are

aggregated particles (ln. 8-9). Applicant's argue that TS-530 fumed silica having an average particle size of 0.02 μm {20 nm} does not read on the claimed invention, as the primary particle size is 20 nm. The examiner notes that claim 1 recites a nanoparticles having a particle diameter of less than 200 nm {see lines 6-7}, and does not specify if the diameter is the primary, aggregated, or agglomerated diameter. As a result, the treated TS-530 silica having a primary particle size of 20 nm meets the claimed limitation of at least 50% by weight of the nanoparticles having a particle diameter of less than 200 nm, as claim 1 fails to specify which diameter {primary, aggregate, agglomerated} is less than 200 nm; i.e. treated TS-530 has a primary particle size of 20 nm, which is a nanoparticle having a diameter of less than 200 nm.

Applicants argue that OX-50 fumed silica having an average particle size of 0.04 μm {40 nm} does not read on the claimed invention, as the primary particle size is 40 nm. The examiner notes that claim 1 recites a nanoparticles having a particle diameter of less than 200 nm {see lines 6-7}, and does not specify if the diameter is the primary, aggregated, or agglomerated diameter. As a result, the silanated OX-50 silica having a primary particle size of 40 nm meets the claimed limitation of at least 50% by weight of the nanoparticles having a particle diameter of less than 200 nm, as claim 1 fails to specify which diameter {primary, aggregate, agglomerated} is less than 200 nm; i.e. treated TS-530 OX-50 has a primary particle size of 40 nm, which is a nanoparticle having a diameter of less than 200 nm.

The examiner notes claim 1 is a product claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) [See MPEP 2113].

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., incorporation of nanofiller in 90 minutes at 1200 rpm with the aid of Dispermat; the mixture dispersed for 1 h at 1000 rpm and subsequently overnight at 500 rpm) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The rejection of claim 11 based upon Angeletakis *et al.* (US 6,121,344) and Teramae *et al.* (US 2002/0022677) or Sato (US 5,773,489) is maintained for reason of record and the following response. Applicants' arguments regarding Angeletakis *et al.* (US 6,121,344) have been sufficiently addressed above. Teramae *et al.* (US '677) was relied on for disclosing dental composite materials (¶ 1) comprising organo-inorganic fillers (¶ 36) prepared by polymerization-covering the surface of an inorganic filler or aggregate filler (¶ 24, 31-33) with a polymerizable monomer, and then grinding it to a proper particle size of 0.5 to 30 μm (¶ 24, 31, 36).

Sato (US '489) was relied on for disclosing dental composite materials (1:5-15) comprising inorganic-organic composite fillers having a particle size of 0.1 to 50 μm (7:33-49; 8:65-9:25) which provide dental restorative materials having superior mechanical strength and abrasion resistance and a suitable consistency and handling, shows a coefficient of thermal expansion close to teeth and a low shrinkage value, and exhibits a suitable transparency and surface smoothness (3:35-43; 29:1-11).

The rejection of claim 25 based upon Angeletakis *et al.* (US 6,121,344) and Teramae *et al.* (US 2002/0022677) or Sato (US 5,773,489) is maintained for reason of record and the following response. Applicants' arguments regarding Angeletakis *et al.* (US 6,121,344) have been sufficiently addressed above. Teramae *et al.* (US '677) was relied on for disclosing dental composite materials (¶ 1) comprising organo-inorganic fillers (¶ 36) prepared by polymerization-covering the surface of an inorganic filler or aggregate filler (¶ 24, 31-33) with a polymerizable monomer, and then grinding it to a proper particle size of 0.5 to 30 μm (¶ 24, 31, 36).

Sato (US '489) was relied on for disclosing dental composite materials (1:5-15) comprising inorganic-organic composite fillers having a particle size of 0.1 to 50 μm (7:33-49; 8:65-9:25) which provide dental restorative materials having superior mechanical strength and abrasion resistance and a suitable consistency and handling, shows a coefficient of thermal expansion close to teeth and a low shrinkage value, and exhibits a suitable transparency and surface smoothness (3:35-43; 29:1-11).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
7-August-10

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796